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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,439	01/26/2001	Kazuko Matsumoto	TOYAM67.001AUS	8038

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EXAMINER	
ZITOMER, STEPHANIE W	
ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,439	MATSUMOTO, KAZUKO	
	Examiner	Art Unit	
	Stephanie Zitomer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 8, 2002 has been entered.

2. Receipt of the amendment filed July 8, 2002 is acknowledged.

3. Rejections not reiterated herein from the previous Final Office Action mailed March 21, 2002 have been withdrawn in view of amendments to the claims and new grounds for rejection. Applicant's arguments in the July 8 amendment have been fully considered but are deemed moot in view of the withdrawal of the rejections.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description: New matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 1 deleting "single stranded" from "collecting the hybridized single stranded nucleic acids" appears to be new matter although this is unclear due to apparent contradictions in the specification. At the bottom of page 17 it is stated that "various known methods can be used [for collecting hybridized single-stranded nucleic acids] so long as each of the hybridized single-stranded nucleic acids can be separated and collected according to immobilized portions of the immobilized nucleic acids...". This would be interpreted by one of skill in the art as collecting single stranded nucleic acids such as after a denaturing step. In fact, such a

procedure is described at the bottom of page 18. However, the description begun at the bottom of page 17 continues on page 18 with the methods recited in claim 1: "Rubbing off only a portion on which the nucleic acids are immobilized, of the nucleic acid-immobilized substrate with a tip of micropipet or the like after the hybridization". This sentence appears to indicate that some of the substrate is removed with the double-stranded nucleic acids resulting from the hybridization still attached to the removed portion of the substrate. Furthermore, the recitation "separating the hybridized single stranded nucleic acids...from the substrate" also has been deleted from claim 1 thus excluding the single strand removal limitation. However, the description of the substrate at pages 4-5 as "plastics", "inorganic polymers" including glass and "metals" which are not known for having flaky or frangible surfaces does not present a clear picture of how rubbing off a portion of the substrate with covalently attached (pages 7-15) nucleic acids may be accomplished, i.e., how both hybridized strands may be removed and collected.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

5. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The method steps in the claims are *non sequitur* to the preamble in that they do not result in "separating" nucleic acids as recited therein. It is suggested to modify the preamble or add a step of "separating" nucleic acids.

(b) Claim 2 lacks antecedent basis in claim 1 because neither the "carbodiimide group" nor the compound-carrying substrate in the recitation "substrate is a substrate carrying a compound having a carbodiimide group" has any relationship to the substrate in the method of claim 1. It is suggested to clarify the relationship between the carbodiimide compound and the substrate.

Rejection under 35 U.S.C. 103(a): Obviousness

6. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (6,007,987) in view of general teachings in the art as exemplified by Rothberg et al. (6,355,423) and Alam (5,635,045). Cantor et al. disclose a method similar to that of the claimed invention set forth in claim 1 wherein a sample nucleic acid solution is

contacted with a nucleic acid-immobilized substrate which provides immobilized portions of single stranded nucleic acids such that single stranded nucleic acids contained in the sample hybridize with the immobilized nucleic acids followed by collecting the hybridized nucleic acids by denaturing elution (column 4, lines 9-17 and lines 58-66). The claimed invention method differs from that of Cantor et al. wherein the hybridized nucleic acids are collected by means of "rubbing off" or "shaving off" the immobilized portions whereas Cantor et al. are silent as to the collecting means. However, the natural phenomenon of transfer of solutes in an aqueous solution by surface wetting via contact between dry and wet surfaces and between wet surfaces was general knowledge in the art. Indeed, the prior art is replete with protocols in which nucleic acids are transferred, i.e., applied to a substrate and removed therefrom, by simple contact. For example, Cantor et al. teach the transfer of nucleic acids from a "master array' to a substrate by simply touching plastic coated pins carrying nucleic acids in solution to a surface to which the nucleic acids are thereby transferred (column 21, lines 32-45). Rothberg et al. teach the use of both manual and robotic methods to transfer nucleic acid probes to a glass surface. Manual transfer was recommended for small arrays and was done by dipping blunt-ended needle tips or pipet tips in the nucleic acid solution and touching them to the surface of a slide (column 82, lines 57-64). Alam describes a method for electroeluting nucleic acids from gels wherein following concentration by electroelution nucleic acids are recovered with a pipet tip (column 6, lines 60-64). Therefore, it would have been ***prima facie*** obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the simple expedient of collecting nucleic acids from the Cantor et al. array substrate by contacting, rubbing or shaving, according to preference, with a pipet, pipet tip or pin and transferring the collected nucleic acids to a vessel for further processing such as sequencing as taught by Cantor et al. (column 4, line 67-column 5, line 1). The skilled practitioner in the art would have been motivated to employ such a simple technique for the obvious benefit of obviating the significant cost of automated equipment.

Regarding the embodiment of claims 3 and 4 wherein the immobilized nucleic acid is DNA Cantor et al. teach that the immobilized nucleic acid is DNA (e.g., column 17, lines 50-56).

Regarding the embodiment of claims 5-8 wherein the substrate has a "plate-shape", "plate-shape" is interpreted as a flat surface such as glass as disclosed by Cantor et al. (column 20, lines 52-56).

7. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (6,007,987) as applied to claims 1 and 3-8 above in view of Takenishi et al. (6,017,742). The claimed invention method of claim 2 differs from that of Cantor et al. wherein the substrate carries a compound having a carbodiimide group. However, Takenishi et al. teach a method of immobilizing nucleic acids on a substrate carrying a carbodiimide group wherein the substrate may be a plate (column 3, lines 52-67; column 11, Example 10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the Takenishi et al. plate carrying a carbodiimide in the method of Cantor. et al. because the skilled practitioner in the art would have been motivated by the routine practice in the art of using carbodiimide chemistry for immobilizing biological molecules on a substrate and by the advantages of ease of handling, reactivity and adhesiveness taught by Takenishi et al. (column 2, lines 39-49; column 3, lines 22-24).

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.

Stephanie Zitomer, Ph.D.
August 26, 2002

STEPHANIE W. ZITOMER
PRIMARY EXAMINER